### THE UNITED STATES PATENT AND TRADEMARK OFFICE

Timothy Norris et al.

Serial No. 09/711,272

Group Art Unit: 1624

Examiner: T. McKenzie November 9, 2000

> STABLE POLYMORPH OF N-(3-ETHYNYLPHENYL)-6, 7-BIS (2-METHOXYETHOXY)-4-QUINAZOLINAMINE HYDROCHLORIDE, METHODS OF PRODUCTION, AND

PHARMACEUTICAL USES THEREOF

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September 18, 2003

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

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SIR:

#### EXPRESS MAIL CERTIFICATE OF MAILING FOR THE ABOVE-IDENTIFIED APPLICATION

"Express Mail" mailing label number: ET 735 980 611 US Date of Deposit: September 18, 2003

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated above and is addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, Mail Stop: RCE.

Respectfully submitted,

√John P. White

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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Timothy Norris et al.

Serial No. : 09/711,272

Group Art Unit: 1624

Filed

November 9, 2000

Examiner: T. McKenzie

For

STABLE POLYMORPH OF N-(3-ETHYNYLPHENYL)-6, 7-BIS (2-METHOXYETHOXY)-4-QUINAZOLINAMINE HYDROCHLORIDE, METHODS OF PRODUCTION, AND

PHARMACEUTICAL USES THEREOF

1185 Avenue of the Americas New York, New York 10036

September 18, 2003

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

# SUPPLEMENTAL AMENDMENT AND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

A Notice of Allowance was issued in connection with the above-identified application by the U.S. Patent and Trademark Office on June 18, 2003 requiring payment of the issue fee by September 18, 2003. Instead of paying the issue fee, applicants are filing a Request for Continued Examination ("RCE") with this Supplemental Amendment and Supplemental Information Disclosure Statement being the "submission" pursuant to 37 C.F.R. §1.114. Accordingly, the subject application is pending today and this Supplemental Amendment and Supplemental Information Disclosure Statement is being timely filed.

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#### In th Specification

Please amend the title of the subject application as follows:

STABLE POLYMORPH OF N-(3-ETHYNYLPHENYLAMINO)-6, 7-BIS (2-METHOXYETHOXY)-4-QUINAZOLINAMINE HYDROCHLORIDE, METHODS OF PRODUCTION, AND PHARMACEUTICAL USES THEREOF

For the Examiner's convenience, Applicants attach hereto a substitute title page as **Exhibit A**.

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# SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants would like to direct the Examiner's attention to the following documents which are listed on Form PTO-1449 (Exhibit B) and are also listed below. A copy of each of the references listed below as items 1-19 is attached hereto as Exhibits 1-19.

Pursuant to 37 C.F.R. 1.98, applicants have listed below and on Form PTO-1449 copending U.S. Application Serial No. 09/355,534. A copy of the specification of the copending U.S. patent application is not enclosed because it is identical with the specification of PCT International Publication No. WO 99/55683, a copy of which was submitted with applicants' June 29, 2001 Information Disclosure Statement as Exhibit 70 and already considered by the Examiner. Thus, applicants are only submitting the currently pending claims of U.S. Serial No. 09/355,534 as Exhibit 7.

- U.S. Patent No. 6,476,040, issued November 5, 2002, Norris et al. (Exhibit 1);
- U.S. Patent No. 6,169,091, issued January 2, 2001,
   Cockerill et al. (Exhibit 2);
- U.S. Patent No. 6,004,967, issued December 21, 1999,
   McMahon et al. (Exhibit 3);
- 4. U.S. Patent No. 5,214,144, issued May 25, 1993, Tai et al. (Exhibit 4);
- 5. U.S. Patent No. 4,281,127, issued July 28, 1981, LeMahieu et al. (Exhibit 5);

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- 6. U.S. Patent No. 3,800,039, issued March 26, 1974, Marquis et al. (Exhibit 6);
- 7. U.S. Patent Application No. 09/355,534, filed July 29, 1999

  (Exhibit 7 pending claims only);
- 8. PCT International Application Publication No. WO 01/034574, published May 17, 2001 (Exhibit 8);
- 9. European Patent Application No. EP 0 837 063 A1, published April 22, 1998 (Exhibit 9);
- 10. Japanese Patent No. 673025, published March 15, 1994

  (Exhibit 10 application with English language translation of cover page, abstract and tables);
- 11. Japanese Patent No. 10036325, published February 10, 1998
   (Exhibit 11 application with English language abstract);
- 12. Japanese Patent No. 10036326, published February 10, 1998
  (Exhibit 12 application with English language abstract);
- 13. Japanese Patent No. 9165385, filed August 25, 1995 (Exhibit
  13 application with English language abstract);
- 14. Russian Patent No. RU 2127263, filed January 15, 1993 (Exhibit 14 application with English language abstract);
- 15. Patent Abridgement of New Zealand Patent No. NZ 0245662, filed January 15, 1993 (Exhibit 15);

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16. Melissaris, A.P. et al., "A Simple and Economical Synthetic Route to p-Ethynylaniline and Ethynyl-Terminated Substrates" (1994) J. Org. Chem. 59: 5818-5821 (Exhibit 16);

- 17. Montalbetti, C. et al., "A Convergent Synthesis of Functionalized B-seco Taxane Skeletons" (1995) Tetrahedron Letters 36(33): 5891-5894 (Exhibit 17);
- 18. Trillo et al., (1993) <u>Tratado de Farmacia Galencia,</u>

  <u>Primeria Edicion</u>, pp. 81, 83, 84 (Exhibit 18 document and translation); and
- 19. Sun Cunji et al., (1981) Yaoxue Xuebao 16(8): 564-570 C.A.
  96 122727 (Exhibit 19 abstract only).

Applicants request that the Examiner review the references and make them of record in the subject application.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

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No fee is deemed necessary in connection with the filing of this Supplemental Amendment and Supplemental Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

John P. White

Registration No. 28,678

Gary J. Gershik

Registration No. 39,992

Attorneys for Applicants

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1185 Avenue of the Americas

New York, New York 10036

(212) 278-0400



## Application for United States Letters Patent

#### To all whom it may concern:

Be it known that, we,

Timothy Norris, Jeffrey W. Raggon, Richard D. Connell, James D. Moyer, Michael J. Morin, Shana M. Kajiji, Barbara A. Foster, Karen J. Ferrante and Sandra L. Silberman

have invented certain new and useful improvements in

STABLE POLYMORPH OF N-(3-ETHYNYLPHENYL)-6, 7-BIS (2-METHOXYETHOXY)-4-QUINAZOLINAMINE HYDROCHLORIDE, METHODS OF PRODUCTION, AND PHARMACEUTICAL USES THEREOF

of which the following is a full, clear and exact description.



